UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

THE UNITED STATES OF AMERICA, and

THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, and WASHINGTON; THE DISTRICT OF COLUMBIA; THE COUNTY OF ALLEGHENY; and THE CITIES OF CHICAGO, NEW YORK, and PHILADELPHIA,

ex rel. JOEL STEVENS,

Plaintiffs,

-V-

ATRICURE, INC., ST. HELENA HOSPITAL, and ADVENTIST HEALTH,

Defendants.

Case No. 1:22-cv-284

Judge Michael R. Barrett

RELATOR'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT ST. HELENA'S AND DEFENDANT ADVENTIST HEALTH'S MOTION TO DISMISS THE FOURTH AMENDED COMPLAINT PURSUANT TO FED.R.CIV.P. 12(b)(1), 12(b)(6), AND 9(b)

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Relator Joel Stevens ("Relator") files this Memorandum of Law in Opposition to

Defendant St. Helena's and Defendant Adventist Health's Motion to Dismiss Relator's Fourth

Amended Complaint, ECF No. 92, filed on August 17, 2022. For the reasons set forth below,

Defendants' motions to dismiss should be denied in their entireties.

I. INTRODUCTION

The Fourth Amended Complaint properly sets forth causes of action as to all federal reimbursement claims tainted by the Defendants' unlawful kickback scheme. Relator alleges that Defendant AtriCure, Inc. ("AtriCure") engaged in an unlawful promotional scheme in concert with Defendants Adventist Health ("Adventist" or "Adventist Health") and St. Helena Hospital ("St. Helena") (Adventist and St. Helena are referred to herein as the "Hospital Defendants") involving the offer and payment of illegal remuneration to healthcare providers and institutions to induce purchases of AtriCure's medical devices, in violation of the federal Anti-Kickback Statute (the "AKS") and the False Claims Act. Fourth Amended Complaint (ECF No. 88; "Complaint" or "Compl.") ¶ 2.

Relator pleads more than enough information to provide the Hospital Defendants with notice regarding these schemes and to state cognizable claims against each of the Defendants under the applicable legal standards in the Sixth Circuit.

II. ARGUMENT

A. Legal Standards

The relevant legal standards are set forth in Relator's *Memorandum of Law in Opposition* to Defendant AtriCure's Motion to Dismiss Relator's Fourth Amended Complaint, filed contemporaneously herewith and incorporated by reference as if set forth in its entirety herein. Relator believes that repeating that discussion here would be duplicative and unnecessarily require judicial resources in reviewing the discussion a second time.

B. Relator's Complaint States a Claim for Relief Under the FCA

As with the discussion of the relevant legal standards, Relator's Complaint adequately sets forth a claim for relief under the False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA"), for the reasons set forth in Relator's Memorandum of Law in Opposition to Defendant AtriCure's Motion to Dismiss Relator's Fourth Amended Complaint, filed contemporaneously herewith and incorporated by reference as if set forth in its entirety herein.

C. The Complaint Satisfies Rule 9(b)'s Particularity Requirement

As discussed in greater detail in the Conspiracy discussion, *infra*, a claim against a group of conspirators need show that Defendants jointly caused presentment of only one claim, rather than that each Defendant separately caused the submission of separate claims. Accordingly, for the reasons set forth in Relator's *Memorandum of Law in Opposition to Defendant AtriCure's Motion to Dismiss Relator's Fourth Amended Complaint*, filed contemporaneously herewith and incorporated by reference as if set forth in its entirety herein, Relator has pled sufficient detail for claims to stand against Defendants St. Helena and Adventist Health, as well as Defendant AtriCure.

D. Relator Sufficiently Alleges Defendants' Conspiracy to Violate the FCA

The Complaint alleges that *all* Defendants violated the federal False Claims Act by virtue of being members of the same conspiracy to submit, or cause to be submitted, false claims in violation of 31 U.S.C. § 3729(a)(1)(C). Hence, Relator will not seek to advance claims against St. Helena or Adventist under 31 U.S.C. § 3729(a)(1)(A) or (a)(1)(B). However, Relator has sufficiently pled claims against St. Helena and Adventist as participants in a conspiracy to commit violations of the False Claims Act in violation of 31 U.S.C. § 3729(a)(1)(C). Here, the "Hospital Defendants" as defined by those defendants in their brief (i.e., St. Helena and its parent Adventist Health System/West), knowingly joined, conspired and participated with AtriCure to

transfer things of value to physicians and EP's for the purpose of inducing or rewarding referral of business reimbursable by federal healthcare programs.

1. Legal Standard for Conspiracy

To adequately allege conspiracy, a relator must establish that "(1) that the defendant conspired with at least one person to get a false or fraudulent claim paid by the Government; and (2) that at least one of the conspirators performed an overt act to get a false or fraudulent claim paid." *United States ex rel. Chase v. LifePath Hospice, Inc.*, No. 8:10-cv-1061-T-30TGW, 2016 U.S. Dist. LEXIS 129405, at *28, 2016 WL 5239863, at *8 (M.D. Fla. Sept. 22, 2016) (citing *United States ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc.*, 597 F. Supp. 2d 1280, 1289 (M.D. Fla. 2009)). "Conspire' in this context requires a meeting of the minds 'to defraud the Government." *Chase*, 2016 U.S. Dist. LEXIS 129405, at *24 (citing *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Here, this means that Defendants must have intended to either submit, or cause the submission of, claims tainted by fraud or kickbacks.

2. <u>Dr. Dunnington, Adventist Health's and St. Helena's Director of Cardio-Thoracic Surgery</u>

A key decisionmaker at Defendant St. Helena with regard to the Hospital Defendants' conspiracy with AtriCure is Dr. Gansevoort ("Gan") Dunnington. Dr. Dunnington's LinkedIn page states that he is "Director of cardiothoracic surgery at Adventist Health" at St. Helena (https://www.linkedin.com/in/gan-dunnington-8421a054, last visited October 4, 2022), and his biography page on AdventistHealth.org states, in part, as follows: "Dr. Gan Dunnington is a board-certified cardiothoracic surgeon, specializing in minimally invasive complex cardiac procedures such as the Hybrid Maze for treatment of atrial fibrillation, mitral valve repair and replacement, transcatheter aortic valve replacement as well as VATS lobectomy for the treatment

of lung cancer." https://doctors.adventisthealth.org/provider/Gansevoort+H+Dunnington-%2C+Jr./1342307. (last visited October 4, 2022).

Dr. Dunnington acted as a bridge between the co-conspirators, getting paid by AtriCure in return for St. Helena's and Adventist Health's role in the scheme. For example, in a recent medical journal paper entitled *Mid-term outcomes of concomitant Cox-Maze IV: Results from a multicenter prospective registry*, published in the *Journal of Cardiac Surgery and sponsored by AtriCure*, Dr. Dunnington is referenced as having a "Conflict of Interest" in connection with this study, described as follows: "G. D.: consultant, speaker, and proctor for AtriCure, Inc." https://onlinelibrary.wiley.com/doi/epdf/10.1111/jocs.16777 (last visited October 4, 2022).

Likewise, in 2016, Dr. Dunnington appeared on an "infomercial" for AtriCure alongside AtriCure's President, Michael Carrel, and was interviewed by former supermodel Kathy Ireland. The description for this video indicates that it was published on September 26, 2016, and the description notation reads: "AtriCure President and CEO, Michael Carrel and Gan H. Dunnington, MD from St. Helena Arrhythmia Center on the sponsored segment on Worldwide Business with Kathy Ireland." https://www.youtube.com/watch?v=llNC2FqY2XQ. At 3:38 and 5:02, this video includes an interior shot of St. Helena Hospital. Repeatedly in this infomercial, Dr. Dunnington's title appears in the video ribbon on screen as: Gan H. Dunnington, MD, Medical Director St. Helena Arrythmia Center. Also scrolling at the bottom of this video is a message reading: "For more information on St. Helena visit: www.AdventistHeart.org/-Arrythmia." At 10:23, there is a shot of a St. Helena sign outside of the facility, and at 12:10, Dr. Dunnington says he is "very happy to be partnering up with AtriCure...."

The co-operation among all three conspirators – including the parallel use of a vineyard location (in this case, Wente Vineyards) to induce people to attend – is plainly visible in the promotion which follows, featuring Dr. Dunnington as the link among them:



https://issuu.com/pleasantonweekly/docs/2017_03_03.pls.section1 at 2 (last visited October 4, 2022). This is an example of the so-called "Patient Education Grants" that Relator alleges Defendant AtriCure paid to its co-conspirators. Compl. ¶ 149

3. <u>Defendants St. Helena and Adventist Health Also Profited From The Scheme</u>

Further, the Complaint alleges a number of AtriCure's inducements were provided directly to Defendant Adventist:

Defendants St. Helena and Adventist solicited from Defendant AtriCure, and in turn Defendant AtriCure agreed to pay (and did pay), Defendant St. Helena and Defendant Adventist illegal remuneration in exchange for inducing sales of its products to Medicare and other government payers under the guise of cash "grants" ostensibly relating to patient education and professional training.

Compl. ¶ 149. "In the case of Defendant St. Helena, AtriCure additionally paid St. Helena cash remuneration in return for hosting surgical teams to perform. . . . procedures onsite." *Id.* ¶ 5. "AtriCure paid St. Helena Hospital to hold these events in 2013. Specifically, Relator was informed that 'you would be surprised how much we are paying St. Helena to do this. They are not doing this for free." *Id.* ¶ 102. Indeed,

Defendant St. Helena . . . routinely served as access point[] for these efforts. In one representative example, in September, 2015, when Mr. Richards was advised that St. Mark's surgeon Vijay Jayankar had been introduced to Dr. Eifling *at a St. Helena training event*, Mr. Richards advised Relator that "this may be what we need to get the program rolling" at "St. Mark's/MountainStar."

Compl. ¶ 148 (emphasis supplied).

Further, the Complaint alleges a number of AtriCure's inducements were provided directly to Defendants Adventist and St. Helena:

Defendants St. Helena and Adventist solicited from Defendant AtriCure, and in turn Defendant AtriCure agreed to pay (and did pay), Defendant St. Helena and Defendant Adventist illegal remuneration in exchange for inducing sales of its products to Medicare and other government payers under the guise of cash "grants" ostensibly relating to patient education and professional training.

Compl. ¶ 149.

"In the case of Defendant St. Helena, AtriCure additionally paid St. Helena cash remuneration in return for hosting surgical teams to perform. . . . procedures onsite." *Id.* ¶ 5. "AtriCure paid St. Helena Hospital to hold these events in 2013. *Id.* ¶102.

Thus, far from being merely innocent bystanders, as set forth *supra* and in Relator's *Memorandum of Law in Opposition to Defendant AtriCure's Motion to Dismiss Relator's Fourth Amended Complaint*, filed contemporaneously herewith and incorporated by reference as if set forth in its entirety herein, Defendant Adventist and one of the hospitals it operates, Defendant St. Helena, are each alleged both to be well aware of this scheme, *and to have been knowing participants* who received kickbacks and other inducements from Defendant AtriCure. Thus, Relator has adequately alleged a conspiracy among all three Defendants.

E. The Complaint Sufficiently Pleads that Defendants' Kickback Scheme Resulted in the Submission of False Claims to State Medicaid Programs

The Court should likewise reject AtriCure's suggestion that, even if Relator's main allegations are upheld, state-and-analogous law counts should be dismissed.

First, AtriCure suggests that Relator has failed to allege that "any conduct whatsoever in the relevant jurisdiction" occurred, AtriCure Mem. at 35 (emphasis in original), but that is simply false. In fact, while Relator might not have identified specific examples, by name, from each jurisdiction, Relator has alleged a nationwide scheme with nationwide conduct: "From at least 2011 to the present (the "Relevant Period"), AtriCure, with the knowledge, involvement and participation of St. Helena and Adventist, engaged in a nationwide, interconnected and ongoing kickback scheme to cause false claims for payment to be submitted to and paid for by federal, state, city and county government healthcare programs." Compl. ¶ 3 (emphasis supplied). Likewise, the Complaint goes on to allege that Defendants "implemented a comprehensive, nationwide and interconnected scheme to pay various forms of remuneration to hospital

systems like Centura Health and Defendant Adventist Health and the hospitals within those systems, to promote and perform certain procedures using AtriCure products." Compl. ¶ 146 (emphasis supplied).). As the Sixth Circuit has affirmed, "[i]f a relator alleges a widespread fraud, then 'a single adequately pled claim of this nature would allow relators to satisfy Rule 9(b)'s pleading requirement and proceed to discovery on the entire scheme." *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 34 F.4th 507, 514 (6th Cir. May 16, 2022).

Further, the Complaint provides examples for inducements paid in many of the Plaintiff States: "During the Relevant Period, AtriCure entered into arrangements with numerous surgeons *nationwide* pursuant to which those surgeons were given cash and/or free products and services by AtriCure," Compl. ¶ 92, and goes on to list specific inducement amounts given to doctors in California, Colorado, Florida, Idaho, Indiana, Missouri, New York, North Carolina, Tennessee, Utah, Washington, and Wisconsin, making dismissal additionally inappropriate as to those exemplar states. *Id.* ¶94.

Relator notes that the Texas Medicaid Fraud Prevention Act ("TMFPA") sets out several unlawful acts that each proscribe specific conduct generally involving the Medicaid program.

See Tex. Hum. Res. Code §§36.002(1)-(13). A majority of the TMFPA's specified unlawful acts do not require the presentment of a "false claim" to incur liability. Tex. Hum. Res. Code §§36.002(1)-(5), (9)-(13). Defendants' suggestion that Relator must plead the presentment or submission of a "false claim" to incur liability is contrary to the plain language of the TMFPA. (ECF No. 91-1 at 7-16; ECF No. 92-1 at 12-16, 19-20). While Defendants summarily conclude that the state statutes are "equivalents" of the FCA (ECF No. 91-1 at 35; ECF No. 92-1 at 1), none undertakes any analysis of the TMFPA. Not one of the cases relied upon by Defendant AtriCure in referencing the state statutes address the TMFPA. ECF No. 91-1 at 35-36.

Defendants St. Helena and Adventist do not cite to a single case in support of their claim that a state statute is merely a "federal counterpart" to the FCA also requiring "proof of a false claim," a requirement that does not apply to the TMFPA. ECF No. 92-1 at 19-20. The cause of action

asserted under the TMFPA in this case must be analyzed "according to [the TMFPA's] plain and

ordinary language," especially where that language differs from the FCA. In re Xerox, 555

S.W.3d 518, 535 (Tex. 2018).

III. **CONCLUSION**

Relator has adequately stated a claim against Defendant AtriCure and its co-defendants.

Relator has alleged detailed examples both of kickbacks and other inducements provided and

received members of Defendants' conspiracy, and of claims caused to submitted, including the

"who, what, where, and when" of each. Further, Relator has adequately alleged that the offering

of these inducements was done with the requisite scienter, and as part of a nationwide scheme,

such that all three Defendants conspired together to violate the FCA and AKS, and the False

Claims Acts of the Plaintiff States and analogous governments are likewise implicated.

For the foregoing reasons, the Hospital Defendants' motions should be denied in their

entireties. In the alternative, Relator should be granted leave to amend a Fifth Amended

Complaint, including to allege any additional facts recited herein, as none of Relator's prior

complaints have yet been tested by a motion to dismiss.

Dated: October 5, 2022

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Respectfully submitted,

/s/ Kelly Mulloy Myers

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CERTIFICATE OF SERVICE

I certify that on October 5, 2022, the foregoing was filed electronically via the Court's authorized electronic filing system. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ Kelly Mulloy Myers